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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,009	10/30/2003	Rok Grahek	2260/119	7405
2101	7590	10/12/2005	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			SHAMEEM, GOLAM M	
			ART UNIT	PAPER NUMBER

1626

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/698,009

Applicant(s)

GRAHEK ET AL.

Examiner

Golam M. M. Shameem, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 13-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/720,952.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 03/01/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

This application is a CIP of 09/720,952 01/03/2001, which is a 371 of PCT/IB99/01553 09/17/1999 and the claim of foreign priority under 35 U.S.C. § 119(a)-(d) to Slovenia P9800241 09/18/1998 is acknowledged.

### ***Information Disclosure Statement***

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 03/01/2004, which has been entered in the file.

### ***Status of Claims***

Claims 1 and 13-17 are currently pending in the application. Claims 1 and 13 have been amended. Claims 2-12 have been canceled.

Receipt is acknowledged of amendment / response filed on July 18, 2005 and that has been entered.

### ***Response to Election/Restriction***

In response to the restriction requirement, Applicants have elected claims 1 and 13-17 (which include Groups I and III) with traverse is acknowledged. Applicant's arguments to rejoin and examine both Groups have been fully considered and found persuasive (Group II has been canceled) and therefore, the Examiner agrees to rejoin and examine claims 1 and 13-17 together on the merits [because they fall within the same scope of invention].

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Tsujita *et al* (6,159,997) and further in view of Olukotun *et al* (US 5,622,985) and Haytko *et al* (US 5,202,029). Applicant claims composition of HMG-CoA reductase inhibitors of high purity.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Tsujita *et al* teach the compositions of HMG-CoA reductase inhibitors containing pravastatin, which are useful for treating arteriosclerosis (see abstract and also claims 140-142). Olukotun *et al* also teach the composition of HMG-CoA reductase inhibitors containing pravastatin sodium salt (column 10, Example 1), their methods of uses thereof. Haytko *et al* (US 5,202,029) teach a process for the purification of an HMG-CoA reductase inhibitor having high degree of purity, such as 99.5 % (see claims 1, 8 and 10).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

Broadly, the composition of HMG-CoA reductase inhibitor containing pravastatin sodium salt taught by Tsujita *et al* and Olukotun *et al* are similar of instantly claimed composition. The differences between the instant claim and that of the prior art references are so negligible (such as purity of at least 99.7% and presence of low level of impurity), that one of ordinary skill in the chemical art would expect slight modifications / variations during purification to be within the expected purview of 35 U.S.C. § 103(a). The disclosure of Haytko

*et al* that teach HMG-CoA reductase inhibitor having high degree of purity, such as 99.5 %, which would easily place Applicants invention in possession of the public at the time of Applicants invention, was filed.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made since the prior art teach the compositions of HMG-CoA reductase inhibitors containing pravastatin with high level of purity which are generic to the instantly claimed invention. Thus one having ordinary skill in the chemical art would be motivated to prepare a composition consisting of a single compound, e.g. pravastatin sodium salt with a reduced level of impurity by the modification of the prior art compositions since one would have reasonable expectation that such modification would make similar compositions and expected to possess similar properties differing only in degree in view of the known teaching of the art. Since the core of compositions of HMG-CoA reductase inhibitors containing pravastatin is not novel and the novelty (if there is any) belongs to the purity level (or presence of total level of impurity), a great caution should be exercised to determine the patentability of the claimed invention. Therefore, in looking at the instant claimed compositions as a whole, the claimed compositions would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

***Objections***

Claims 13-17 are objected as being dependent upon a rejected base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is 571-273-8300. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golam M M Shameem, Ph.D.  
Primary Examiner  
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Technology Center 1600



**GOLAM M. M. SHAMEEM, PH.D**  
**PRIMARY EXAMINER**

September 19, 2005